APR 7 2006

K060492

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Craniofacial Plate & Screw System
23 February 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
800-258-1946 (phone)
610-791-6882 (fax)
matt.hull@aesculap.com (email)

TRADE NAME: Aesculap Craniofacial Plate & Screw System

COMMON NAME: Craniofacial plates and screws

CLASSIFICATION NAMES: Bone plate/ Intraosseous fixation screw/ Burr hole cover/ Preformed nonalterable cranioplasty plate

REGULATION NUMBERS: 872.4760/ 872.4880/ 882.5250/ 882.5330

PRODUCT CODES: JEY/ DZL/ GXR/ GXN

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the additional plates and screws are described here are substantially equivalent to the craniofacial plates and screws previously cleared in the Aesculap Premarket Notification #K923705.

DEVICE DESCRIPTION

The Aesculap Craniofacial Plate and Screw System consists of various sizes and shapes of plates and several lengths of 1.5mm screws (to include 1.8mm emergency screws). The screws are manufactured from Titanium forged alloy Ti6Al4V and the plates from CP Titanium (Ti Grade 2).

INDICATIONS FOR USE

The Aesculap Craniofacial Plate and Screw System is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new components of the Craniofacial Plate & Screw System are offered in similar in shapes and sizes as the predicate devices. The plates are manufactured from CP Titanium which is the same material as the predicate devices, the new screws will be made of a Titanium Alloy.

PERFORMANCE DATA

The screws were tested per ASTM F543 for pull-out and torque while the plates were tested per ASTM F382 for bending.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Matthew M. Hull
Regulatory Affairs Manager
Aesculap®, Incorporated
3773 Corporate Parkway
Center Valley Pennsylvania 18034

Re: K060492
Trade/Device Name: Aesculap Craniofacial Plate and Screw System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 23, 2006
Received: March 1, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

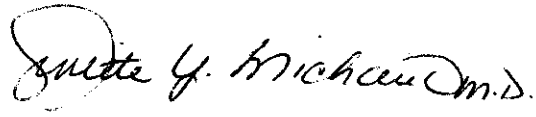
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K060492

Device Name: Aesculap Craniofacial Plate and Screw System

Indications for Use:

The Aesculap Craniofacial Plate and Screw System is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ology, General Hospital,
...l Devices

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